LeMaitre®

PhasTIPP® Resector Handpiece

PhasTIPP® Resector Handpiece
Instructions for Use - English

PhasTIPP® Resector Handpiece

(Model Number 5002-01)
Instructions for Use - English

Preface

The LeMaitre Vascular PhasTIPP Resector consists of the non-sterile Resector Handpiece and the sterile Disposable Resector. This manual contains information you need to operate and maintain the LeMaitre Vascular PhasTIPP Resector Handpiece. It is essential that you read and understand all of the information in this manual before using or maintaining the system.

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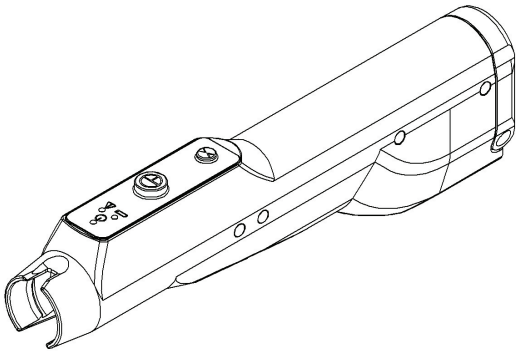
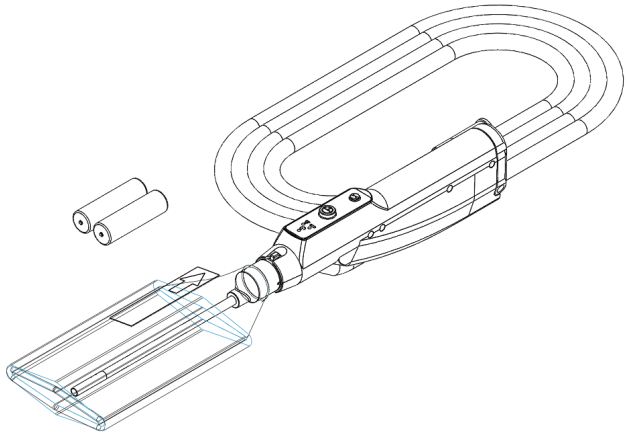
PhasTIPP Resector Handpiece



PhasTIPP Resector Handpiece attached to Disposable Resector



Device Description
The LeMaitre Vascular PhasTIPP Resector Handpiece is a reusable device that provides controls for the operation of the rotating blades on the Disposable Resector (REF 5002-45 and 5002-55). The Resector Handpiece is used to morcellate and to remove targeted varicosities when connected to the Disposable Resector and a suction pump. The distal stainless steel resector blade on the Disposable Resector is the applied part of the device. The Resector Handpiece is provided non-sterile and must be covered with the microbial barrier sheath in the sterile field. The Resector Handpiece must not be sterilized or exposed to liquids.

The Resector Handpiece is intended for use by vascular or general surgeons for treatment of patients of all ages and sexes that require removal of varicose veins. It is classified as a continuous use device.

The Resector Handpiece is intended to be used in combination with the LeMaitre Vascular PhasTIPP Illuminator components.

Indications for Use
The PhasTIPP system is indicated for use in ambulatory phlebectomy procedures for the resection and ablation of varicose veins. The Illuminator is also indicated for use without the Resector for visualization of varicose veins and infusion of tumescent solution during an ambulatory phlebectomy case.

Essential Performance
The Resector Handpiece will only actuate the motor when a button is pressed (either motor power or window lock).
The Resector Handpiece is designed such that the user is always in control of the motion of the motor. The Resector Handpiece is designed to be resistant to electromagnetic disturbances and is compliant with 60601-1-2, however if in the rare event that essential performance is degraded due to electromagnetic disturbances, the motor may actuate without pressing the window lock or motor power button.

Contraindications
Use of the PhasTIPP Resector components is contraindicated in situations where ambulatory phlebectomy is contraindicated.

Warnings
Please read this manual before using the PhasTIPP Resector Handpiece. These operating instructions will make the system easier to use and ensure optimal performance and reliable use. As with any surgical instrument, there are important health and safety considerations. These are listed below and reiterated within the text.

Following the maintenance recommendations and warnings outlined in this document are required to maintain safe and effective use.

1. When removing the Resector Handpiece from the shipping box, inspect contents to ensure that no damage is evident. Contact your LeMaitre Vascular Representative if damage is noted.
2. Before using the Resector Handpiece for the first time, you should review all available product information. Surgeons should become familiar with this surgical technique and the PhasTIPP components. Surgeons should be experienced in ambulatory phlebectomy surgery using powered instruments. Healthy tissue can be injured by improper use of the resector. Use every available means to avoid such injury.
3. The Resector Handpiece is only intended for use in a clinical environment.
4. The Resector Handpiece and the Disposable Resector are intended to be used together. They must be used as supplied. Do not interchange disposable components. Please read the PhasTIPP Disposable Resector Instruction for Use (R3941) before using these PhasTIPP devices.
5. **The outer surface of the Resector Handpiece should be isolated from the sterile field during clinical procedures. Prior to and after use, it should be wiped with liquid chemical disinfectants commonly used in health care facilities to clean plastic reusable medical devices.**
6. DO NOT STERILIZE - The Resector Handpiece is provided non-sterile, and should never be subjected to sterilization (e.g. Autoclave). Mechanical and electrical damage will occur if the Resector Handpiece is subjected to chemical or pressurized steam (autoclave) sterilization. Sterilization will void the product warranty.

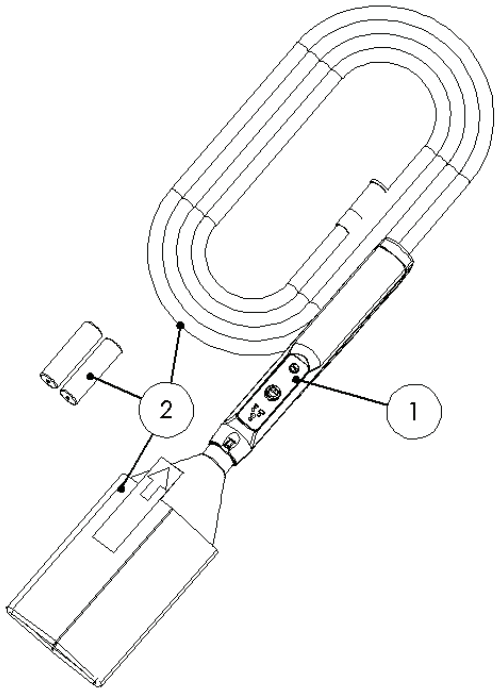
7. DO NOT SUBMERGE OR SPRAY – The Resector Handpiece should never be submerged or sprayed with water or cleaning agents. Submerging or spraying the device with water will void the product warranty.
8. Do not allow any cleaning agent to drip into the battery compartment or the distal opening of the Resector Handpiece.
9. The distal end of the Disposable Resector contains moving sharp blades. Use caution when operating the device so that the tip of the shaft is only exposed to areas where resection is desired. Do not attempt to clear debris from the blades by hand.
10. If visualization is lost during any point in the procedure, stop resecting immediately.
11. Use only the battery supplied with the disposable set to power the unit. Use of alternate batteries or other power sources may permanently damage the equipment, or cause errors or malfunction
12. Do not store the device with batteries installed. Batteries must be discarded after a case is complete and new batteries loaded just prior to the next case.
13. Excessive pressure of the Disposable Resector against the vessel, or prolonged activation in a stationary position may cause the blades to perforate through the skin.
14. In the unlikely event that the device is malfunctioning and will not stop rotating (unresponsive to buttons), first press and hold both buttons simultaneously to halt rotations. Continue to hold the buttons until the device is safely removed from the patient. If that is unsuccessful, remove the batteries from the device.
15. No modification of this equipment is allowed. There are no serviceable components inside. Dismantling the equipment will void the warranty.
16. **DANGER**: Risk of explosion if used in the presence of flammable anesthetics.
17. The use of accessory equipment not complying with IEC 60601 or equivalent safety requirements may lead to a reduced level of safety of the PhasTIPP system.
18. Do not allow the battery or battery contacts to touch the patient and user simultaneously in order to prevent a conductive circuit between the patient, user, and device.
19. If defibrillation is necessary during procedure, stop the phlebectomy procedure and remove PhasTIPP components from patient and surgical table if possible. The PhasTIPP components are not defibrillation proof, so if they are contacting the patient or the surgical table, do not touch any of the PhasTIPP components during defibrillation.
20. If electrosurgery is necessary during procedure, use caution to prevent any emission effects via radiated and conducted current interference through the patient.

Potential Complications

- Bruising
- Hematoma
- Hemosiderin deposits

Precautions

1. U.S. Federal law restricts this device to sale by or on the order of a physician.
2. Prior to use, examine the device(s) for possible damage to assure proper functionality. If damaged, do not use.
3. Verify that the Preoperative Setup has been successfully completed (see "Preoperative Setup for Use in a Surgical Procedure" section).
4. Only the LeMaitre Vascular PhasTIPP Disposable Resector can be used with the Resector Handpiece. The Disposable Resector is for single use only. Do not resterilize or lubricate the Resector assembly. Dispose of the Resector after use.
5. Use of a resterilized Disposable Resector may permanently damage, impede performance, or cause failure of your other LeMaitre Vascular PhasTIPP devices. Use of such products may render any warranties null and void.
6. Remove batteries before cleaning the Resector Handpiece.
7. Do not allow the rotating portion of the Resector to touch any metallic object, such as Illuminator components. Damage to both instruments is likely. Damage to the Resector can range from a slight distortion or dulling of the blade edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures, dulling, or if you have any other reason to suspect the device is damaged, replace it immediately.
8. This unit complies with IEC 60601-1. However, the user must be aware that this does not necessarily ensure protection of the unit against interference from other devices.
9. Handle the device with care. If the device is dropped or damaged in any way, it must be returned to LeMaitre Vascular, Inc. immediately for service.
10. This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
    a. Reorient or relocate this equipment, the other equipment, or both.
    b. Increase the separation between the pieces of equipment.
    c. Consult a biomedical engineer.
11. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.



System Components

The PhasTIPP System consists of a variety of components.

1. Resector Handpiece, Non-Sterile

The Resector Handpiece is a hand-held battery operated device that provides on /off button control for the operation of the oscillating motion of the Disposable Resector. It also provides a window lock button to control the position of the oscillating shaft when it stops and LED indicator lights to display the status of the device. Please see the PhasTIPP Resector Handpiece Instructions for Use (R3942) for additional information.

2. Disposable Resector, Sterile

The Disposable Resector provides a rotating distal shaft and suction tube that connects the Resector Handpiece in order to remove the targeted varicosities. Also included in the disposable is a microbial barrier sheath to cover the Resector Handpiece, and a non-sterile disposable battery for the Resector Handpiece. The distal hub on both sizes is a dark teal color that matches a dark teal stripe on the Resector Handpiece, which is intended to aid in connecting the correct disposable to the correct handpiece. The Resector assembly is available in two different shaft outer diameters (OD) and the proximal hub on these two sizes vary: 4.5mm OD (5002-45, green) and 5.5mm OD (5002-55, pink). Please see the PhasTIPP Disposable Resector Instructions for Use (R3941) for additional information.

3. Illuminator Handpiece, Non-Sterile

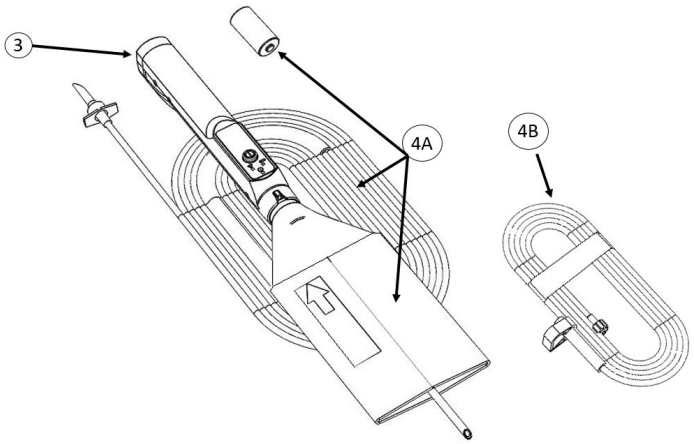
The Illuminator Handpiece is a hand held battery operated device that provides on / off button control for the

operation of the intense white light output from the Illuminator Disposable. It also provides LED indicator lights to display the status of the device. It is designed to be used along with a foot switch-operated peristaltic pump (not included) to provide control of the tumescent infusion flow rate. Please see the PhasTIPP Illuminator Handpiece Instructions for Use (R3939) for additional information.

4. Disposable Illuminator, Sterile

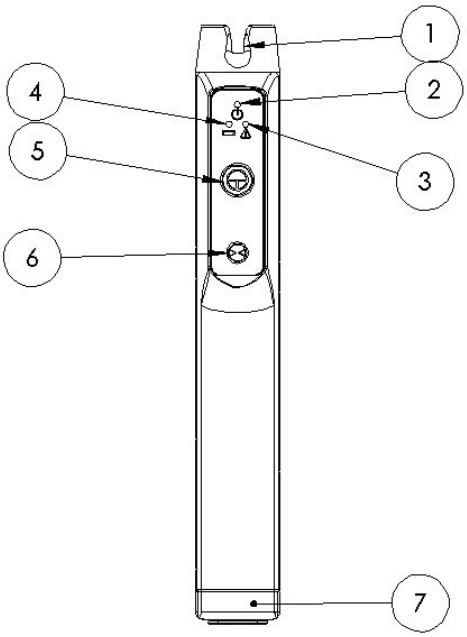
The Disposable Illuminator (4A) provides a light shaft to connect to the Illuminator Handpiece in order to transilluminate the targeted varicosities. Also available as an accessory is the Illuminator Injection Tubing (REF 5003-01) (4B) to inject tumescent fluid from an IV bag (not included) via a needle (not included). A microbial barrier sheath covers the Illuminator Handpiece, and a non-sterile disposable battery for the Illuminator Handpiece. The hub on the disposable is a light teal color that matches a light teal stripe on the Illuminator Handpiece, which is intended to aid in connecting the correct disposable to the correct handpiece. Please see the PhasTIPP Disposable Illuminator Instructions for Use (R3940) for additional information.

Required accessories that may be purchased separately include a vacuum source, infusion pump, and storage cases.



Unpacking the Components

Carefully unpack and inspect all of your LeMaitre Vascular PhasTIPP components. If any parts are missing or damaged, contact your LeMaitre Vascular representative. Save the box and packing materials in the event a component must be returned for repair. When not in use, the handpiece should be stored in a LeMaitre Vascular PhasTIPP Storage Case (REF 5000-01 or - 02).



① Connection slot for the PhasTIPP Disposable Resector
② LED Status Indicator for Standby
③ LED Status Indicator for System Fault
④ LED Status Indicator for Low Battery
⑤ On/Off Control Button to oscillate Resector blade
⑥ Window Lock Control Button allows user to set home position of inner blade
⑦ Battery Door

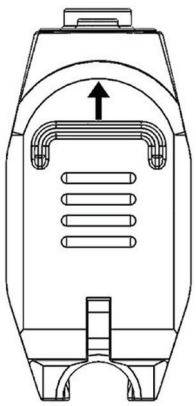
PhasTIPP Resector Handpiece and Controls

To Open Battery Door

1. Slide the battery cover in the direction of the arrow (see figure).
2. The door will pop open.

To Close Battery Door

1. Fully extend the battery cover.
2. Close the battery cover against the handpiece.
3. Slide the battery cover in the direction opposite of the arrow on the battery door (see figure).



To open: Slide battery door in direction of arrow

To close: Slide battery door against direction of arrow

Preoperative Setup for Use in a Surgical Procedure

There are three main steps for preparing the Resector Handpiece for use in a surgical procedure:

1. Wipe down the outer surfaces of the Resector Handpiece with a disposable chemical disinfectant wipe or a with a clean damp cloth and mild germicide commonly used in health care facilities to clean plastic reusable medical devices. Do not allow any cleaning agent to drip into the battery compartment or the distal opening of the handpiece.

WARNING: The Resector Handpiece should never be subjected to sterilization (steam, chemical, or otherwise) and never submerged or sprayed with water or cleaning agents.

2. Open the battery door on the proximal end of the Resector Handpiece by sliding the door forward (the door

will automatically pop open after unlatched). Load the batteries from the PhasTIPP Disposable Resector package into the Resector Handpiece in the correct orientation and close battery door. Verify the green LED turns on.

3. Consult the PhasTIPP Disposable Resector Instructions for Use (R3941) for additional setup information related to the disposable.

NOTE: Reference troubleshooting section if yellow or red indicator lights are on.

Resector Control

Reference the Cautions section prior to operation.

Verify that the Preoperative Setup has been successfully completed.

There are two button controls on the Resector Handpiece. The Window Lock button determines the stop position of the inner tube relative to the opening in the outer tube. Press and hold the Window Lock Set button to set the Window Lock. The inner Resector blade will slowly rotate while the button is pressed. Release the button when the Window Lock has reached the desired position. The window can be fully opened or closed, or somewhere in between, depending on the technique requirement.

Press and hold the On/Off control button to oscillate the resector blade for clinical use. The inner tube and blade will oscillate (2 revolutions in each direction) only while the button is depressed and return to and stop at the window lock position when the button is released. Cutting takes place when the edge of the inner tube rotates across the assembly's outer tube at the tip of the distal shaft. The oscillating action alternately opens and closes the window to modulate the suction flow. The oscillation speed is set at 400RPM and is not adjustable by the user.

If the yellow low battery indicator light is on, obtain new batteries from a new PhasTIPP Disposable Resector.

If the red indicator LED is flashing slowly, the device is in the anti-stall routine. During the anti-stall routine, the device detects resistance during resection and responds by reversing direction and then continuing with an RPM of 600 instead of 400 (higher cutting power). The device will continue in the anti-stall routine for five attempts before the device stops and the red indicator LED becomes solid. During the anti-stall routine, continue to hold the on/off button until the anti-stall routine successfully clears the tissue or until the red indicator LED becomes solid and oscillation stops. The oscillation button can be released and pressed again to perform another anti-stall attempt.

If the anti-stall routine fails to clear the obstruction, the user must carefully remove the device, using caution not to tear any tissue jammed inside the resector. Do not forcefully pull or rip the jammed resector out of the patient. Once out of the patient, inspect the device for any jams that may need to be cleared either by resecting in air or a saline bath or by removing tissue with forceps. Do not attempt to remove obstruction via forceps while operating the device and never attempt to remove obstruction by hand.

If the red light is flashing quickly or is solid, consult the Troubleshooting section.

The non-sterile Resector Handpiece is designed to be isolated from the sterile field during clinical procedures by a plastic, see-through microbial barrier sheath that is deployed from the disposable component and over the Resector Handpiece. Operation of the Resector Handpiece-buttons and visibility of the status indicators in the operating room (OR) is intended only through the plastic microbial barrier sheath.

Resector Clinical Use Instructions

1. Make vertical incisions of 2-3mm in length strategically around surgical site. Use the minimum number of incisions to gain access. For varicose vein removal a minimum of two incisions are required, one on either end of the varicosity (generally one distal and one proximal). One access point will be used for infusion/illumination and another for resection.
2. Insert the tip of the Illuminator into one incision at a shallow angle and use the foot pedal to deliver tumescent anesthesia into the surgical site through the peristaltic pump. Tumescent solution is recommended as it will create a fluid pocket around the target vein to aid in visualization and also cause the vein to spasm, pushing blood out of the vein to eases removal.
3. Insert the tip of the resector into the other incision in the subcutaneous space under or on the side of the vein. Skin over the varicosity should be held taut with an open hand. With the illuminator on, begin resecting the varicose vein by holding down the button on the resector hand piece and laterally moving the devices in sync, so that the varicosity and tip of the resector are always visible.

NOTE: Do not use a sweeping motion under the skin as it may increase bruising. Instead remove device completely and re-insert in a new direction.

4. Switch the illuminator and resector positions or make additional incisions as required to completely resect the varicose tissue. After the resecting is complete, turn off the illuminator and remove the devices from the surgical site at shallow angles.
5. Using a surgical punch, it is recommended that drainage holes be created around the surgical site. Use the Illuminator and tumescence to irrigate the surgical site until drainage holes run clear.
6. If the battery indicator turns on during use, stop procedure and obtain a new disposable. Follow Disposable Postoperative Procedure Instructions to disconnect devices and Post Use Instructions with a new battery and disposable (batteries cannot be replaced without compromising sterility so a new disposable is required.)

Postoperative Procedure

Follow these steps after each procedure:

1. Disconnect and dispose of the Disposable Resector and tubing used during the procedure following standard protocols for disposal of biohazardous waste.

CAUTION: Disposable Resector and tubing used with the Resector Handpiece are for single use only. Do not resterilize. Discard after use.

2. Open the battery door and dispose of the batteries following standard protocols for battery waste. Close and secure battery door.
3. Wipe down the outer surfaces of the Resector Handpiece with a disposable chemical disinfectant wipe or a with a clean damp cloth and mild germicide commonly used in health care facilities to clean plastic reusable medical devices. Do not allow any cleaning agent to drip into the battery compartment or the distal opening of the Resector Handpiece.

WARNING: The Resector Handpiece should never be submerged or sprayed with water or cleaning agents.

WARNING: The Resector Handpiece should never be subjected to sterilization (steam, chemical, or otherwise).

4. When not in use, store the Resector Handpiece in a PhasTIPP Storage Case (REF 5000-01 or -02).
5. This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment, it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Resterilization/Re-use

The PhasTIPP Resector Handpiece is a reusable device. It is supplied non-sterile and is not intended to be sterilized. During use, it must be shielded from the sterile field by the sterile microbial barrier sheath attached to the Disposable Resector.

Electrical Interference

CAUTION: This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment.
- Consult a biomedical engineer.

Environmental Protection

CAUTION: This equipment contains electronic printed circuit assemblies and lithium ion batteries. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Service

All service and repairs should be performed by LeMaitre Vascular. Contact LeMaitre Vascular Customer Service prior to returning the device to request a Return Goods Authorization (RGA) number. Items to be serviced should be carefully repackaged and returned per instructions provided by LeMaitre Vascular Customer Service.

NOTE: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or damaged due to liquid or sterilization will incur additional costs, regardless of warranty status.

See "Ordering Information" for a list of replacement parts

Troubleshooting and Service Indications

When in use, the PhasTIPP Resector Handpiece runs a diagnostic routine in the background, checking for power level from the battery and any other system faults. When the system detects a condition that requires attention, the yellow or red indicator LED will become illuminated and the green indicator LED on the Resector Handpiece will turn off. In some cases, the system will continue to operate normally, but in other cases the device will not function. If the procedures below do not resolve the problem, the unit should be returned to LeMaitre Vascular for service.

#	Symptom	Possible Cause	Remedy
1	The green 'Standby' LED indicator fails to turn on.	The device does not have enough power.	• Confirm presence of a batteries. • Confirm the battery door is latched closed. • Confirm proper orientation of the batteries. • Obtain a new set of batteries from a PhasTIPP Disposable Resector.
		The Resector Handpiece is defective.	• Return Resector Handpiece to LeMaitre Vascular for service or replacement.
2	The yellow 'Low Battery' LED indicator is on (solid).	The device does not have enough power.	• Obtain a new set of batteries from a PhasTIPP Disposable Resector.
		The Resector Handpiece is defective.	• Return Resector Handpiece to LeMaitre Vascular for service or replacement.
3	The yellow 'Low Battery' LED indicator is flashing.	The battery is critically low.	• Obtain a new set of batteries from a PhasTIPP Disposable Resector.
4	The red 'Fault' LED indicator is on (solid).	There is an issue with the battery power.	• Obtain a new set of batteries from a PhasTIPP Disposable Resector.
		The Resector Handpiece is defective.	• Return Resector Handpiece to LeMaitre Vascular for service or replacement.
5	The red 'Fault' LED indicator is flashing slowly.	The device is experiencing difficult to remove varicosities.	• Pull back and operate the Resector in a fluid pocket. • Slowly advance again using caution not to overload the device's power.
6	The resector stops responding to button presses and the red "Fault" LED indicator flashes quickly.	The Resector Handpiece is experiencing a hardware problem.	• If this occurs once and then operates normally, the Resector Handpiece may be used as usual.
			• If this occurs repeatedly, return Resector Handpiece to LeMaitre Vascular for service or replacement.
7	Resector Handpiece will not run or runs erratically.	The PhasTIPP Disposable Resector is not properly connected.	• Replace the PhasTIPP Disposable Resector.
		The PhasTIPP Disposable Resector is defective.	
		The device does not have enough power.	• Obtain a new set of batteries from a PhasTIPP Disposable Resector.
		The Resector Handpiece is defective.	• Return Resector Handpiece to LeMaitre Vascular for service or replacement.
8	The Resector will not stop rotating.	The Resector Handpiece is defective.	• Press and hold both buttons to stop rotations. • Remove batteries to cut power to device. • Return Resector Handpiece to LeMaitre Vascular for service or replacement.
9	Miscellaneous Device Malfunction / Overheating	The Resector Handpiece is defective.	• Press and hold both buttons to stop rotations. • Remove batteries to cut power to device. • Return Resector Handpiece to LeMaitre Vascular for service or replacement.

Technical Specifications – PhasTIPP Resector Handpiece

Dimensions:	1.1" wide x 2.1" deep x 7.6" long
Weight:	1 lb
Power:	Tadiran TLM-1550HP, Lithium Ion 4V Battery, Non-Rechargeable, Qty 2
Ambient Operating Temperature:	15°C ~ 30°C
Atmospheric Pressure:	70kPa - 106kPa
Storage Temperature:	15°C ~ 30°C
Environmental Humidity Range:	30-70% RH
Equipment Classification:	BF type applied part. The equipment is internally powered The Resector Handpiece is not rated for protection against harmful ingress of water. Do not use the Resector Handpiece in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide.

Firmware version: 1.0.1
Maximum Transit and Storage Temperature Limit: 60°C
Minimum Transit and Storage Temperature Limit: -29°C

Ordering Information – PhasTIPP Components and Accessories

REF	*DESCRIPTION*
5000-01	PhasTIPP Small Storage Case (handpieces only)
5000-02	PhasTIPP Medium Storage Case (handpieces & infusion pump)
5001-01	PhasTIPP Illuminator Handpiece
5001-02	PhasTIPP Illuminator Peristaltic Infusion Pump (optional)
5001-03	PhasTIPP Disposable Illuminator
5002-01	PhasTIPP Resector Handpiece
5002-45	4.5mm PhasTIPP Disposable Resector
5002-55	5.5mm PhasTIPP Disposable Resector
5003-01	PhasTIPP Illuminator Injection Tubing

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The PhasTIPP Resector Handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the Resector Handpiece should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Resector Handpiece uses RF energy only for its internal functions. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Resector Handpiece is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The PhasTIPP Resector Handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the Resector Handpiece should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment –Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV 8kV contact ± 8kV 15kV air	± 6kV 8kV contact ± 8kV 15kV air	Floors should be wood, concrete or ceramic tile and the relative humidity should be between 30-70%.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	30 A/m	The power frequency magnetic field should be at levels
RFID Immunity 134.2kHz (IEC 61000-4-39)	65A/m	65A/m	Do not expose device above tested level
RFID Immunity 13.56MHz (IEC 61000-4-39)	7.5A/m	7.5A/m	Do not expose device above tested level
Electrosurgery Interference Susceptibility (IEC 60601-2-2 Annex BB.4)	Cutting and Coagulation	Cutting and Coagulation	User should mitigate emission effects when using in combination with HF surgical equipment

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment –Guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the LeMaitre Vascular PhasTIPP System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2 √(p..) d=1.2 √(p..) 80 MHz to 800 MHz d=2.3 √(p..) 800 MHz to 2.5 GHz Where "p" is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
a) Field strengths from fixed transmitters, such as base stations for radio, (cellular/cordless) telephones, land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PhasTIPP device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PhasTIPP device.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note: The EMC performance is not affected by the connection of the infusion tube.

Guidance for Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and PhasTIPP Devices			
The PhasTIPP Resector Handpiece is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Resector Handpiece can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PhasTIPP device(s) as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter W	**Separation distance according to frequency of transmitter M**		
	150 kHz to 80 MHz $d=1.2\sqrt{p}$	80 MHz to 800 MHz $d=1.2\sqrt{p}$	800 MHz to 2.5 GHz $d=2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Warranty

Limited Product Warranty; Limitation of Remedies

LeMaitre Vascular, Inc., warrants that reasonable care has been used in the manufacture of this device and that this device is suitable for the indication(s) expressly specified in these instructions for use. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the date that is 12 months from the date of invoice for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

Training Program

Training opportunities are available at Surgeon Training Centers. For next available dates please contact your local Sales Representative, email csus@lemaitre.com, or call LeMaitre Vascular at 800-628-9470 (US).

Symbol Legend

		Distributed By:	Rx only					
English	Symbol Legend	Distributed By	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician.	On-Off push control	Window Lock	Waste electrical and electronic equipment	Non-ionizing electromagnetic radiation	EQUIPMENT CLASSIFICATION—Type BF Applied Part

REF	SN	LOT	Safety tested Production monitored TÜV SÜD US			NON STERILE	US		DO NOT AUTOCLAVE	NOT DISPOSABLE
Catalog Number	Serial Number	Batch Code	TUVus SUD 60601 Safety Certification	Keep dry	Consult instructions for use	Non-sterile	Date/ Country of Manufacture	Manufacturer	Do Not Autoclave	Not Disposable

						60˚C -29˚C	UDI
System Fault	Battery Orientation	Standby	Low Battery	Caution	Fragile, handle with care	Storage/ Transit Temperature Limit	Unique Device Identifier

Distributed By:

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